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| 09/786,725 | 04/23/2001 | Hans-Werner Heinrich | 101195-44 | 4120 |
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| LONDA, BRUCE S. NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022 | | | EXAMINER WILLIAMS, KAREN M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/786,725

Applicant(s)

HEINRICH ET AL.

Examiner

JAMES L. GRUN

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May and 27 Aug 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 12-15 and 25-38 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 12-15 is/are allowed.
- 7) ☒ Claim(s) 25-38 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Paper No(s)/Mail Date: ____

DETAILED ACTION

Amendment Entry

The amendments filed 31 May and 27 August 2012 are acknowledged and have been entered. Claims 25-38 are newly added. Claims 1-11 and 16-24 have been cancelled. Claims 12-15 and 25-38 remain in the case.

Specification

The disclosure is objected to because of the following informalities: reference to the prior filed application, and the relationship of the applications (e.g., --This application is a 371 of PCT/DE99/02816, filed 03 September 1999.--), must be included in the first sentence(s) of the specification following the title or in an application data sheet.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

Applicant teaches that the antibodies as instantly claimed in claim 30 are highly specific for elastase 1 and are not cross-reactive (see e.g. Substitute Specification, pages 5-9). Thus, applicant's disclosure does not provide written or enabling support for the invention as is now claimed wherein such antibodies are used to identify or detect plural iso-enzymes in a sample.

Applicant's arguments filed 31 May 2012 have been fully considered but they are not deemed to be persuasive. Applicant's amendment necessitated the new ground(s) of rejection under this statute presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25 and claims dependent thereupon, "the" formation lacks antecedent basis.

In claim 29, "the" formation lacks antecedent basis.

In claim 30 and claims dependent thereupon, the interrelationships of the components and steps of the method are not clear because the antibodies are specific for elastase 1 epitopes and thus "identification" or determination of amounts of "elastase iso-enzymes" (i.e. plural iso-enzymes) are not clear. In these claims "the" identification lacks antecedent basis.

In claim 33, the interrelationships of the components and steps of the method are not clear because the function of the two different antibodies are not clear, it is not clear that the immobilized antibody is at least one of the previously recited antibodies, and it is not clear what applicant intends as encompassed by a "suitable detection system" or how one determines suitability.

In claim 34 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 36 and claims dependent thereupon, the interrelationships of the components and steps of the method are not clear because it is not clear that the immobilized antibodies are at least one of the previously recited antibodies, and it is not clear what applicant intends as encompassed by a "suitable detection system" or how one determines suitability.

In claim 37, the interrelationships of the components and steps of the method are not clear because it is not clear that the antibodies are at least one of the previously recited antibodies and it is not clear how the antibody "part[s]" interrelate.

In claim 38, it is not clear what applicant intends as encompassed because it is not clear that the antibodies are at least one of the previously recited antibodies and it is not clear for what applicant intends the antibodies as cross-reactive.

Applicant's arguments filed 31 May 2012 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above. Indeed, applicant's amendment necessitated the new ground(s) of rejection under this statute presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 33 and 36-38 are rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. The rejected claims fail to include all the limitations of the claim upon which each depends because these claims do not appear to require the antibodies of claim 30. With further regard to claim 38, applicant teaches that the antibodies of claim 30 are highly specific for elastase 1 and are not cross-reactive (see e.g. Substitute Specification, pages 5-9). Applicant may cancel the claim(s), amend the claim(s) to

place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Applicant's arguments filed 31 May 2012 have been fully considered but they are not deemed to be persuasive. Applicant's amendment necessitated the new ground(s) of rejection under this statute presented in this Office action.

Claims 12-15 are currently allowable.

Remarks

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sziegoleit et al. (Clin. Biochem. 22: 79, 1989) teach elicitation of polyclonal antibodies to purified enzyme in several animal species, including rabbits ,and the enzyme preparation used would inherently have been a mixture of at least the elastase I isoforms (i.e. elastases IIIA and IIIB), comprising some of the peptides as instantly claimed. The reference teaches a sandwich enzyme-linked immunosorbent assay for diagnosis of pancreatitis or pancreatic cancer by determining pancreatic elastase 1 using the polyclonal antibodies.

Scheefers et al. (U.S. Pat. No. 5,622,837)2 teach determinations of pancreatic elastase 1 in serum and stool samples as indicative of pancreatic disease. The

reference teaches determinations with sandwich immunoassays involving antibodies, preferably monoclonal, elicited to different epitopes of the protein, including the use of antibodies specific for particular epitopes therein elicited by immunization with purified enzyme or fragments thereof, as a sensitive alternative to radioimmunoassay. The referenced also teaches elicitation of polyclonal antibodies to purified elastase.

Tani et al. (J. Biol. Chem. 263: 1231, 1988) teach the amino acid sequences encoded by human elastase genes (see Fig. 9). The reference teaches that the sequence identified therein as elastase I is not expressed in human adult pancreas (see page 1231, col. 2) and that the sequences identified therein as elastase III are human elastase I as known to the art (see page 1237, col. 2).

Harlow et al. teach that, once the amino acid and/or nucleic acid sequences of a protein are known, it is routine and conventional in the art to elicit antibodies to peptides and/or fusion proteins derived from the protein and/or to prepare a bank of site-specific monoclonal antibodies for use (pages 72-77). Harlow et al. teach rationales for the selection of synthetic peptides as immunogens and suggest the carboxyl-terminal or amino-terminal peptide sequences or internal hydrophilic regions as desirable starting peptide immunogens (page 76).

Geokas et al. (J. Biol. Chem. 252: 61, 1977) teach an immunoassay for human elastase II in human serum and the elevation of the enzyme therein in individuals with acute pancreatic inflammation (see page 66, col. 2).

Schneider et al. (Clin. Chem. 51: 1052, 2005) teach complications if antibodies in a human elastase detection assay bind to porcine elastases.

The abstract of Weiss et al. (published variously in: J. Ped. Gastroenterol. Nut.; Pancreatology; and Pancreas) teaches that antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase do not bind to all isoforms of elastase. Further experimentation is taught as required by the reference for one to assess the specific differences and prognostic value of elastase isoforms in the assessment of exocrine pancreatic insufficiency.

Stein et al. (Clin. Chem. 42: 222, 1996) teach the clinical evaluation of the fecal elastase assay of Scheefers et al. (US 5,622,837).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
October 22, 2012

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641
10/22/12